

10 things to know about the proposed European Biotech Act: Positioning EU as Biotech Powerhouse

Turning health innovation into real solutions for patients EU

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#EUBiotech



1 STRENGTHENS EUROPE'S COMPETITIVENESS

The proposed European Biotech Act presents a comprehensive set of measures to strengthen Europe's biotechnology and biomanufacturing ecosystem and turn scientific excellence into tangible innovation and industrial capacity.



3 REINFORCING EU SOVEREIGNTY

The Act proposes measures to streamline and harmonise regulatory processes, reinforcing Europe's ability to develop, scale and manufacture biotechnologies in Europe.



5 BRINGING IDEAS TO THE MARKET

The measures proposed in the Act aim to incentive research, investment and industrial production, to help innovative companies bring health biotech solutions to the market and scale-up within Europe.



7 BOOSTING INVESTMENT

The proposed Act foresees access to finance for biotech and start-ups by mobilising public and private capital, de-risking innovation, and supporting scale-up across the EU.

AIM: MOBILISING €10 BILLION

The BioTechEU initiative (2026–2027), in collaboration with the EIB Group, aims to mobilise €10 billion to address the financing gap faced by biotech SMEs and start-ups.



9 SUPPORTING HIGH IMPACT HEALTH BIOTECHNOLOGY STRATEGIC PROJECTS

Strategic projects would benefit from coordinated support and streamlined procedures at Member State level. High-impact strategic projects would receive EU-level recognition, and facilitated access to EU funding. The proposed Act also promotes cooperation across networks of health biotech cluster to upscale research and facilitate transfer knowledge.



2 ONE ACT, FAR-REACHING IMPACTS

Through coordinated actions, the proposed European Biotech Act aims to simplify rules, mobilise investment, foster innovation, and improve public health resilience.



4 HEALTH AND BEYOND

Starting from health biotechnology, the proposed European Biotech Act sets the stage for a broader and stronger cross-sector EU biotech ecosystem.



6 AI AT THE CENTRE

The proposed European Biotech Act employs a 'digital by default' approach using AI testing environment to accelerates drug discovery, clinical trials and biomanufacturing.



8 SPEEDING UP CLINICAL TRIALS

The proposed Biotech Act aims to improve the EU framework for clinical trials (CT), helping innovative therapies reach patients more quickly.

CLINICAL TRIAL APPLICATION BEFORE VS AFTER



Cutting Clinical Trial approval timelines, fostering greater collaboration across borders, and improving regulatory efficiency, without compromising safety, quality, or ethical standards.



10 IMPROVING BIOSECURITY

The proposed Act aims to strengthen coordination and oversight to prevent the misuse of biotech while supporting Europe's preparedness for emerging biotechnological risks.